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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,134	09/14/2006	Irina Velikyan	PH0334	7198
36335 7590 08/27/2009 GE HEALTHCARE, INC. IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231				
EXAMINER				
PERREIRA, MELISSA JEAN				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,134

Applicant(s)

VELIKYAN ET AL.

Examiner

MELISSA PERREIRA

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-16 are pending in the application. Claim 16 was withdrawn from consideration in the amendment filed 6/9/09.

Response to Arguments

1. Applicant's arguments filed 6/9/09 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (WO03/059397) in view of the combined disclosures of Yngve (Int. Diss. Abs. **2001**, 62) and Bottcher et al. (US 5,439,863) and in further view of Maier-Borst et al. (GB 2056471A) as stated in the office action mailed 3/9/09.

4. Applicant requests why the amount/concentration of chelating agent required for reaction with $^{68}\text{Ga}^{3+}$ needs to be provided.

5. The amount/concentration of chelating agent is not required but applicant asserts that in the present invention it is possible to reduce the amount of chelating agent in a subsequent complex formation reaction, which considerably increases the specific radioactivity.

6. The method of the instant claims does not provide for the amounts/concentrations of gallium or chelating agent required for reaction with $^{68}\text{Ga}^{3+}$ or the specific radioactivity of radiolabeled gallium complex. The instant claims merely recite, "reacting a $^{68}\text{Ga}^{3+}$ radioisotope with a chelating agent". The method of Griffiths et al. for producing a radiolabeled gallium complex involves reacting the solution of a peptide labeled macrocyclic chelate with the ^{68}Ga diluted from the $^{68}\text{Ge}/^{68}\text{Ga}$ titanium dioxide generator which can be fitted with an anion-exchange membrane. The method of Griffiths et al. encompasses the method for producing a radiolabeled gallium complex of the instant claims and is capable of producing an increase in specific radioactivity of radiolabelled gallium complex.
7. Applicant does not provide any assertions with regards to the cited prior art but does state that in the present invention, ^{68}Ga is eluted from a commercial generator already in ionic form.
8. Maier-Borst et al. teaches that the ^{68}Ga released by the ion exchanger is in ionic form in high yield (Maier-Borst et al., p1, lines 59-63).
9. Applicant asserts that in the instant application, the preconcentration of ^{68}Ga which is needed for the efficiency of the labeling complexing reaction.
10. The instant claims do not provide the limitations of a preconcentration procedure.
11. Applicant asserts that the chelating ^{68}Ga -labeling reactions are sensitive to the presence of competing metals ions therefore it is important to purify the $^{68}\text{Ge}/^{68}\text{Ga}$ eluate from those elements.

12. The method of producing a radiolabeled gallium complex of Griffiths et al. involves reacting the solution of a peptide labeled macrocyclic chelate with the ^{68}Ga diluted from the $^{68}\text{Ge}/^{68}\text{Ga}$ titanium dioxide generator which can be fitted with an anion-exchange membrane.

13. Maier-Borst et al. discloses the separation of ^{68}Ga from its parent nuclide with water via passing the eluate from a generator column into an anion exchanger comprising quaternary ammonium groups incorporated in a matrix of styrene and divinylbenzene and washing the anion exchanger with water.

14. Therefore it would have been obvious to one skilled in the art to purify the ^{68}Ga of Griffiths et al., generated from the $^{68}\text{Ge}/^{68}\text{Ga}$ titanium dioxide generator, from its parent nuclide or competing metal ions with water via passing the eluate from a generator column into an anion exchanger, such as that taught by Maier-Borst et al.

15. Applicant asserts that, unlike the prior art, the present invention discloses a concentration of $^{68}\text{Ga}^{3+}$, which is in the picomolar to nanomolar to micromolar range after the elution in an anion exchanger. Hence, it is possible to reduce the amount of chelating agent in a subsequent complex formation reaction, which considerably increases the specific radioactivity.

16. First, the instant claim 16 comprising the limitation "wherein the eluting $^{68}\text{Ga}^{3+}$ is in the picomolar to nanomolar range after the elution, a more preferably in a nanomolar to micromolar level" is withdrawn from consideration.

17. Second, Griffiths et al. teaches that the advantage of the ^{68}Ga generator of the disclosure is that ^{68}Ga is eluted without unwanted over-dilution where the prior art

teaches of ^{68}Ga eluted from previous generators is present in extremely dilute solution, typically under one picomole per milliCurie. Therefore, it would have been obvious to one skilled in the art to generate $^{68}\text{Ga}^{3+}$ from the ^{68}Ga generator of Griffiths et al. to provide for $^{68}\text{Ga}^{3+}$ in the picomolar to nanomolar range after the elution or a nanomolar to micromolar level.

Double Patenting

18. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

19. Claims 1,3-7 and 15 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-14 of copending Application No. 10/552,206.

20. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

21. The rejection is maintained as the claims of the copending application has not been amended or cancelled.

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,8-15 and 19 of copending Application No. 10/522,206.

Claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 8-14 of copending Application No. 11/358,681.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Applicant asserts that terminal disclaimers will be filed once the instant application is indicated to be allowable.

The rejections are maintained since terminal disclaimers have not been filed.

New Grounds of Objection Necessitated by the Amendment

Claim Objections

23. Claim 1 is objected to because of the following informalities: the instant claim recites, "and wherein the ." at the end of the claim. Appropriate correction is required.

Conclusion

24. No claims are allowed at this time.

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELISSA PERREIRA** whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618